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| EXAMINER |
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NGUYEN, TUAN VAN

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| ART UNIT | PAPER NUMBER |
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3731

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|--|------------|---------------|
| 3 MONTHS | 02/01/2007 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/615,625

Applicant(s)

COOK ET AL.

Examiner

Tuan V. Nguyen

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 June 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Amendment After Non-Final Rejection

1. According to the Amendment After Non-Final Rejection applicants filed on November 22, 2006, applicant amend claims 1-3, 7, 15, and 17-19, and cancels claim 20. Now, claims 1-19 are pending in this present application.

Response to Amendment

2. Applicant's arguments filed on November 22, 2006 with respect to Pedlick reference that does not disclose the suture anchor that is configured to toggle and anchor inside a bone cavity based on tension being applied to a suture in the suture channel have been fully considered and persuasive therefore, the 102 rejections based solely on Pedlick reference is hereby withdrawn.
3. Applicant's arguments filed on November 22, 2006 with respect to Donnelley reference that does not disclose a suture channel formed in an elongated body wherein the suture channel is oriented substantially transverse to a longitudinal axis of symmetry of the body have been fully considered but not persuasive. Examiner respectfully traverses the applicant's remarks: Since the definition of the word "transverse" according to the Merriam-Webster's Collegiate Dictionary, Tenth Edition principal copyright 1993, page 1256, is *acting, lying, or being across : set crosswise*. Therefore, the suture channel 24 as shown in Figures 1A and 1B is

being cross with the longitudinal axis of symmetry (axis L shown in Figure 1A) meet the "transverse" limitation as claimed by applicant.

4. Applicant's arguments filed on November 22, 2006 with respect to Donnelley reference that does the center of the opening is laterally offset with respect to the longitudinal axis of symmetry of the elongate body have been fully considered but not persuasive. Examiner respectfully traverses the applicant's remarks: here it is noted that examiner interpret the limitation "a center" means a point. What abundantly clearly from the figure 1A is that the center of the opening as shown on the front face 18 or the center of the opening as shown on the back face 18 is positioned offset or laterally offset with respect to the longitudinal axis of symmetry of the elongate body 12. Perhaps applicant intended to claim that the centerline of the suture channel is laterally offset with respect to the longitudinal axis of symmetry of the elongate body.
5. Applicant's arguments filed on November 22, 2006 with respect to Donnelley reference that does not teach the anchor is for use in small bone. Examiner respectfully traverses the applicant's remarks: nowhere in the disclosure of Donnelley states that the anchor is not use in small bone. Donnelley suggested that in general his anchor can be used for attaching soft tissue to hard bone (see Field of the Invention) furthermore, Donnelley discloses that the width at the widest portion of the second trailing end is 3mm and also suggested that his anchor is smaller than conventional bone anchors (see col. 4, lines 35-43).

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6. Applicant amends claims 2, 3, 17, and 18 to overcome the objection therefore, the objection in previous Office action is hereby withdrawn.
7. With respect to the Bartlet reference (U.S. 5,626,612), examiner recited the reference as the prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. **Claims 1, 3-13, 15-16, 18 and 19-20 is rejected under 35 U.S.C. 102(e) as being anticipated by Donnelly et al. (U.S. 6,773,436).**
10. Referring to claims 1, 3-13, 15-16, 18, and 19-20, Donnelly discloses (see Figs. 1-2C, 4a-4b and 9A-9D) a bioabsorbable suture anchor 10 for anchoring tissue to a bone, comprising: an elongate body 12 defined by a longitudinal axis L; a first, leading end 14, includes a rounded distal end, and a second, trailing end 16; the width of the second trailing end is 3 mm at its widest portion (see col. 8, lines 19-21); the elongate body comprising two opposed surfaces 12 between the first and second ends, and a plurality of sidewalls 20, extending between the two opposed

surfaces; a flared portion, includes biting edge 22 formed on the second end and extending from one of the sidewalls, the flared portion being adapted to engage and anchor into bone tissue; and a suture channel 24, that includes rounded edge 28 on both sides, formed in the elongate body for passage of a suture strand 2 (see Fig. 2a) therethrough, the suture channel extending between the two opposed surfaces, and strand of suture is inserted through the channel, and the center of the channel is offset from the longitudinal axis of the anchor (see Fig. 4a and 4b); wherein the suture anchor is configured to toggle and anchor inside a bone cavity by the pulling on the suture (see col. 8, lines 50-53); and the anchor also includes a blind hole 30 for engaging with insertion tool 400 (see Fig. 9), Figure 9 shown the insertion tool having elongate member the elongate member can be use as a handle, and a distal, attachment end (see col. 3, line 43 to col. 4, line 65). Donnelly also discloses the method of deployment the anchor into a bone hole as claimed in claims 19-20 (see col. 8, lines 17-65 and claims 19-20).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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12. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. **Claims 2, 3, 14, 15, 17, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Donnelly et al. in view of Donnelly et al.**

14. Referring to **claims 2, 3, 17, and 18**, Donnelly discloses the diameter size of suture anchor is 3 mm and the suture anchor having an overall size smaller than conventional bone anchors (see col. 4, lines 35-43). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to design a suture anchor having elongate body is in the range of about 2-6 mm and the width of the anchor is about 1 mm to about 3 mm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

15. Referring to **claim 14**, Donnelly discloses the suture anchor may be made of bioabsorbable or non-bioabsorbable polymer (see col. 4, lines 62-68 and col. 6, lines 26-32). It is old and well known in the art that polymer and Titanium has its own natural color. The natural color of the material that made the suture anchor can be used as visual indication by the naked eyes of the surgeons during the

surgery or by X-ray after the surgery (if the material is Titanium) for the indication of the location of the anchor in the surgical site. Therefore, it would have been obvious matter of design choice to one of ordinary skill in the art at the time the invention was made by the applicant to use blue dye because Applicant has not disclosed that the blue dye provides an advantage, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Donnelly device, and applicant's invention, to perform equally well.

16. Referring to **claim 15**, Donnelly discloses the invention substantially as claim except for the insertion tool 400 having a handle. Figure 9 of Donnelly reference shown the insertion tool having an elongate member, wherein the elongate member can be use as a handle. In any event, here it is noted that the insertion tool for deployment of a suture anchor having a handle that attached to the proximal end of the elongate member is old and well known in the art.
17. **Claims 2, 3, 17, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Donnelly et al. in view of Cassidy (U.S. 6,280,474).**
18. Referring to **claims 2, 3, 17, and 18**, Donnelly discloses the invention substantially as claimed except for a specific range of the length of the anchor from about 2 mm to about 6 mm and the width at the widest point of the anchor is about 1 mm to about 3 mm. Here it is noted that Donnelly discloses the dimension of the width at the widest point of the anchor is 3 mm and the overall dimension of the anchor is smaller than conventional bone anchors (see col. 4, lines 35-43). However, Cassidy discloses a bone anchor can be used to attached small bone to small

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bone or soft tissue to bone (see Figures 11B and 6B and col. 3, lines 29-38) wherein the overall dimensions of the anchor is 1 mm to about 6 mm wide and between 3 mm to 30 mm long (see col. 3, lines 62-65). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made by the applicant to design a suture anchor having elongate body is in the range of about 2-6 mm and the width of the anchor is about 1 mm to about 3 mm for a specific bone in the body, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tuan V. Nguyen whose telephone number is 571-272-5962. The examiner can normally be reached on M-F: 9:00 AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, AnhTuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Tuan V. Nguyen
January 25, 2007


ANH TUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER
1/25/07